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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Inventor: Massimo Fini, et al

Patent No.: 6,834,650 B1

Serial No.: 10/018,899

Issued: December 28, 2004

Filed: June 6, 2002

For: FACE OR NOSE MASK FOR NON-
INVASIVE VENTILATION OF PATIENTS
IN GENERAL

Examiner: Henry Bennett
Mital Patel

Group Art Unit: 3743

Docket No.: MALCC-59155

February 23, 2005
Los Angeles, California

Certificate
MAR 03 2005
of Correction

REQUEST FOR CERTIFICATE OF CORRECTION

Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The above-identified patent has been found to have the errors set forth in the enclosed Certificate of Correction. It is requested that this Certificate of Correction be issued and returned to us. Since the errors occurred in the final printing phase of the patent, no fee is enclosed. However, should the Office determine that a fee is required, please charge our account no. 06-2425.

The errors are verifiable in the patent application file as follows:

MAR 9 2005



PATENT

<u>ERROR</u>	<u>VERIFICATION</u>
Column 1, line 45, after "times." add new paragraph before "Within". Column 2, line 38, delete "chamber" and insert --chamber 10--. Column 3, line 12, delete "concept" and insert --concept--. Column 3, line 12, after "concept." add new paragraph before "All". Column 4, line 11, delete "chamber, and" and insert --chamber, and--. Column 4, line 13, delete "sequentially" and insert --sequentially--.	See page 2, line 2 of Specification. See page 3, line 18 of Specification. See page 4, line 21 of Specification. See page 4, line 20 of Specification. See page 2 of Amendment after Final Rejection dated June 18, 2004. See page 2 of Amendment after Final Rejection dated June 18, 2004.

We respectfully request that this Certificate of Correction be expeditiously issued since the errors reported herein were incurred through the fault of the United States Patent and Trademark Office.

Attached hereto, in duplicate, is Form PTO-1050, with at least one copy being suitable for printing.

A duplicate of this document is attached.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

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JWP/pp

Enclosures

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Serial No.: 10/018,899
Atty. Docket: MALCC-59155

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**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO. : 6,834,650 B1
DATED : December 28, 2004
INVENTOR(S) : **Massimo Fini, et al**

It is certified that errors appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, line 45, after "times." add new paragraph before "Within".
Column 2, line 38, delete "chamber" and insert --chamber 10--.
Column 3, line 12, delete "concept" and insert --concept--.
Column 3, line 12, after "concept." add new paragraph before "All".
Column 4, line 11, delete "chamber,and" and insert --chamber, and--.
Column 4, line 13, delete "sequentially" and insert --sequentially--.

80868.1

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PATENT NO. 6,834,650 B1

No. of additional copies

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This collection of information is required by 37 CFR 1.322 and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief of Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450 Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORM TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

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portion is possible at all times.

Within the scope of this aim, a particular object of the present invention is to provide a face or nose mask in which the perfect seal of the mask with respect to the outside is ensured at all times but the region where pressure is applied to the skin changes continuously.

Another object of the present invention is to provide a mask in which the system for inflating the sealing element is independent of the ventilation system, consequently allowing a wide range of adjustment for the pressure values used.

Another object of the present invention is to provide a mask which, by way of its particular constructive characteristics, is capable of giving the greatest assurances of reliability and safety in use.

Another object of the present invention is to provide a face or nose mask for non-invasive ventilation of patients in general which can be easily obtained starting from commonly commercially available elements and materials and is also competitive from a purely economical point of view.

This aim, these objects and others which will become apparent hereinafter are achieved by a face or nose mask for non-invasive ventilation of patients in general, according to the invention, which comprises a mask body provided with an inlet for connection to a ventilation apparatus and perimetrically provided with a sealing element for application to the face of a patient, characterized in that said sealing element comprises at least one first chamber and at least one second chamber which can be connected separately to a source of pressurized air.

Further characteristics and advantages of the present invention will become apparent from the following detailed description of a preferred but not exclusive embodiment of a face or nose mask for non-invasive ventilation of patients in general, illustrated only by way of non-limitative example in the accompanying drawings, wherein:

Figure 1 is a partially sectional schematic view of the mask according to

the invention with the seal provided by one chamber; and

Figure 2 is a view of the mask with the seal produced by the other chamber.

With reference to the above figures, the face or nose mask for non-invasive ventilation of patients in general, according to the invention, generally designated by the reference numeral 1, comprises a mask body 2 which has the conventional configuration of a face or nose mask and is provided with an inlet 3 for connection, by means of a hose 4, to a ventilation apparatus.

10 In the perimetric region, the mask has a flange 5 at which the sealing element for application to the face of the patient is provided.

The particularity of the invention is constituted by the fact that the sealing element is provided by at least one first chamber 10 and by at least one second chamber 11 which are advantageously arranged side by side, the first chamber being arranged outside with respect to the second chamber.

The chambers have separate connections to a source of pressurized air, and in particular there is provided a first connector 12 for the first chamber 10 and a second connector 13 for the second chamber 11; such connectors are connected to an inflation device which is constituted for example by extremely compact micropumps which can be actuated sequentially so as to release the pressure in one chamber and inflate the other chamber, thus ensuring the seal.

The inflation and deflation rate can be adjusted in any manner, since it is independent of the ventilator of the ventilation system.

25 In practice it is possible to alternate inflation and deflation with a period of a few seconds, consequently having the advantage that the skin is affected in the same region for a period which is substantially halved, but most of all with the advantage that in practice blood flow is never interrupted or hindered, thus preventing the occurrence of pain and dangerous sores.

In practice, the system adopted consists in removing pressure from one chamber and simultaneously restoring pressure in the other chamber, so that the seal is ensured at all times but the region where pressure is applied to the skin changes.

5 Advantageously, the chambers have a closed perimeter, but from the conceptual point of view there is no difference if the chambers 10, 11 affect only portions of the face and in any case the regions that are more severely affected by pain or sores, depending on the pressure applied in order to provide the seal.

10 From the above description it is thus evident that the invention achieves the intended aim and objects, and in particular the fact is stressed that a face mask is provided which has an inflatable sealing element which is entirely autonomous and independent of the ventilator used for ventilation, thus
~~allowing to adjust the pressure inside the individual chambers independently~~
15 ~~of each other and to provide alternating deflation and inflation of the~~
~~chambers at a rate which can be adjusted at will in view of the fact that the~~
chambers are separately connected to a source of pressurized air, for example constituted by micropumps.

20 The invention thus conceived is susceptible of numerous modifications and variations, all of which are within the scope of the inventive concept.

All the details may also be replaced with other technically equivalent elements.

In practice, the materials employed, as well as the contingent shapes and the dimensions, may be any according to requirements.

IN THE CLAIMS:

Claim 1 (Currently amended) In a face or nose mask for non-invasive ventilation of patients in general, comprising a mask body provided with an inlet for connection to a ventilation apparatus and perimetrically provided with a sealing element for application to the face of a patient, the improvement in said face or nose mask wherein said sealing element comprises at least one first inflatable chamber and at least one second inflatable chamber, said at least one first inflatable chamber having a first connector connectable to a source of pressurized air, and said at least one second inflatable chamber having a second connector connectable to the source of pressurized air, [[and]] said second inflatable chamber capable of being inflated separately from said first chamber, and said first and second inflatable chambers being alternately inflated and deflated sequentially independently of ventilation provided by the ventilation apparatus.

Claim 2 (Currently amended) The mask according to claim 1, wherein said first and second inflatable chambers have a closed perimeter.

Claim 3 (Currently amended) The mask according to claim 1, wherein said first and second inflatable chambers ~~chamber~~ lie concentrically side by side.

Claims 4-6 (Cancelled)